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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

CHEYENNE VERBISH, et al.,

Plaintiffs,

v.

COLGATE-PALMOLIVE COMPANY,

Defendant.

CASE NO. 3:25-CV-00426-TLT

DEFENDANT COLGATE-PALMOLIVE COMPANY'S MOTION TO DISMISS PLAINTIFFS' COMPLAINT OR STRIKE CERTAIN ALLEGATIONS

Date: June 17, 2025
Time: 2:00 p.m.
Judge: Trina L. Thompson
Location: Courtroom 9, 19th Floor

Complaint Filed: January 13, 2025
Trial Date: None

NOTICE OF MOTION

PLEASE TAKE NOTICE that on June 17, 2025 at 2:00 p.m., or as soon thereafter as the matter may be heard by the Honorable Trina L. Thompson (Courtroom 9 of the U.S. Courthouse located at 450 Golden Gate Avenue, San Francisco, CA 94102), Defendant Colgate-Palmolive Company ("Colgate") will, and hereby does, move the Court under Federal Rules of Civil Procedure ("Rules") 12(b)(1), 12(b)(2), 12(b)(6), and 9(b) to dismiss Plaintiffs' Complaint in its entirety, or alternatively under Rule 12(f) to strike certain allegations.

Colgate seeks an order under Rule 12(b)(1) dismissing all claims asserted by all Plaintiffs because they fail to establish Article III injury. Plaintiffs' claims should also be dismissed under Rule 12(b)(6) because they are preempted by federal law and under Rules 12(b)(6) and 9(b) because Plaintiffs fail to plead with particularity any deceptive conduct as a matter of law, and because they fail to allege statutory standing and the injury elements necessary to state each of their claims. Additionally, Colgate seeks an order under Rule 12(b)(2) dismissing the New York Plaintiffs' New York Claims and the Illinois Plaintiffs' Illinois claims because the Court lacks personal jurisdiction over such claims. Alternatively, should the Court find that any of Plaintiffs' claims survive dismissal, Colgate seeks an order pursuant to Rule 12(f) striking certain immaterial and/or scandalous allegations (Dkt. 1 ¶¶ 20-21, 24-27, 124-60) that do not bear on Plaintiffs' theory of liability.

This motion is based on this notice, the accompanying memorandum of points and authorities, the concurrently-filed Request for Judicial Notice and accompanying Declaration of Robyn Bladow and attached exhibits, any reply in support of this motion, and any oral argument the Court may entertain.

Dated: April 14, 2025

Respectfully submitted,

/s/ Robyn E. Bladow
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KIRKLAND & ELLIS LLP

Attorneys for Defendant
Colgate-Palmolive Company

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

Cases

Statutes

Rules

Other Authorities

MEMORANDUM OF POINTS AND AUTHORITIES

I. INTRODUCTION

Colgate-Palmolive Company is a leading manufacturer of oral care products, including toothpastes containing fluoride, which is widely recognized as helpful in preventing cavities in adults and children. Plaintiffs are parents who chose to purchase for their children certain fluoride toothpastes sold by Colgate-Palmolive Company and Tom's of Maine, Inc. (collectively, for purposes of this motion, "Colgate"), and who then filed this lawsuit to challenge the products' labeling. Although their Complaint is littered with alarmist allegations about the supposed dangers of children ingesting too much fluoride, Plaintiffs' alleged injuries have nothing to do with fluoride, much less its safety. Instead, the Complaint turns entirely on whether certain product packaging somehow misled Plaintiffs into permitting their children to use too much toothpaste—contrary to labeling directions on both the cartons and tubes telling them *exactly* how much toothpaste to use. Plaintiffs allege their use of the products (contrary to the directions) resulted in "less brushings per tube" (¶¶ 251, 259, 271, 279, 286)[1] and they seek economic damages based on their theory that they used up the toothpaste faster than they should have (¶¶ 230, 233). Plaintiffs' claims fail for multiple independent reasons:

First, this Court lacks subject matter jurisdiction over Plaintiffs' claims because their purported theory of economic loss based on "fewer brushings per product" is not fairly traceable to any conduct by Colgate, whose product labels do not promise any number of brushings. Plaintiffs therefore fail to plead Article III standing.

Second, the Court lacks personal jurisdiction over the non-California Plaintiffs' claims because they do not arise out of any California contacts.

Third, Plaintiffs' claims are expressly preempted by federal law. The Food and Drug Administration ("FDA") has detailed the labeling requirements for fluoride products in the Anticaries Monograph, which establishes the conditions under which the products are deemed "safe, effective, and not misbranded." 21 C.F.R. §§ 330.1, 355.1. To ensure national uniformity in labeling, Congress enacted an express preemption provision, 21 U.S.C. § 379r(a), which *prohibits* plaintiffs from bringing state claims

[1] Undesignated "¶" citations are to the Complaint, Dkt. 1. All emphasis is added unless otherwise noted.

that seek to impose requirements "different from or in addition to" or "otherwise not identical with" federal law. Plaintiffs' claims are preempted because they seek to impose additional or different restrictions on Colgate.

Fourth, Plaintiffs' state-law claims fail for additional reasons, including because they do not plausibly allege—let alone plead with particularity—how a reasonable consumer would be deceived by the packaging features they claim are deceptive or that they suffered actual injury, nor can they bring equitable claims because they fail to allege an inadequate legal remedy.

Finally, although the Court should dismiss the Complaint in its entirety for the aforementioned reasons, it should alternatively strike under Rule 12(f) Plaintiffs' inflammatory and immaterial allegations about the supposed risks of physical injury and death from ingesting fluoride (¶¶ 20-21, 24-27, 124-60)—an unnecessary detour that has nothing to do with their claims.

II. STATEMENT OF ISSUES TO BE DECIDED

- Whether Plaintiffs' failure to plead the requisite injury in fact necessary to establish Article III standing warrants dismissal for lack of subject matter jurisdiction.
- Whether the non-California Plaintiffs' claims should be dismissed for failing to establish personal jurisdiction because they do not arise from any California contacts.
- Whether Plaintiffs' state-law claims are expressly preempted by federal law because they attempt to impose requirements that are different from, in addition to, or otherwise not identical with governing federal regulations.
- Whether Plaintiffs' state-law claims fail for additional reasons, including because they fail to plausibly allege or plead with particularity any conduct that would mislead a reasonable consumer or that they suffered actual injury, and because they fail to allege legal remedies are inadequate, requiring dismissal of any equitable claims.
- Whether Plaintiffs' scandalous, immaterial, and impertinent allegations about fluoride, which have nothing to do with their claims, should alternatively be stricken under Rule 12(f).

III. STATEMENT OF RELEVANT FACTS

Colgate manufactures and sells several fluoride-containing toothpaste products. The FDA regulates these fluoride toothpastes, which are regulated as over-the-counter ("OTC") drugs, through a "monograph" process.[2] A monograph is a set of detailed regulations describing the conditions under which

[2] The CARES Act overhauled the way the FDA administers the OTC monograph process by converting existing monograph regulations to administrative orders and replacing notice-and-comment rulemaking with an administrative order process. *See* Coronavirus Aid, Relief, and Economic Security Act, Pub. L. No. 116-136, § 3851, 134 Stat. 281, 435 (2020). The previous process is summarized in this motion because the FDA published the final monograph for anticaries drug products in 1995. The current

a category of drugs may be marketed without individualized FDA review and approval. *See* 21 C.F.R. § 330.10; 21 U.S.C. § 355h. The monograph is developed only after the FDA has appointed an advisory panel of independent qualified experts, which reviews the data and reports its "conclusions and recommendations" to the FDA "with respect to the safety and effectiveness of the drugs." 21 C.F.R. § 330.10(a)(1), (3) ("Procedures for Classifying OTC Drugs as Generally Recognized as Safe and Effective and not Misbranded, and for Establishing Monographs").

Relevant here, the FDA "establish[ed] conditions under which [OTC] anticaries drug products (products that aid in the prevention of dental cavities) are generally recognized as safe and effective and ***not misbranded***." *Anticaries Drug Products for Over-the-Counter Human Use; Final Monograph* ("Anticaries Monograph"), 60 Fed. Reg. 52474 (Oct. 6, 1995); *see also* 21 C.F.R. § 355.10 (applying Anticaries Monograph to products containing sodium fluoride and sodium monofluorophosphate at concentrations consistent with the Products, as defined below). Before finalizing the Anticaries Monograph, the FDA considered "the accidental ingestion rate for fluoride toothpaste" among children, the associated risk of dental fluorosis, and whether to approve "the safety and effectiveness of a low-fluoride dentifrice for children 2 to under 6 years of age." *Id.* at 52475-76, 52486-87; *see* ¶¶ 182-90. The FDA then required anticaries products to include the following warnings and directions on their labels, which are spelled out in the Anticaries Monograph:

1. Warning: "**Keep out of reach of children under 6 years of age**. If more than used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center right away." 21 C.F.R. § 355.50(c)(1).

2. Directions: "Adults and children 2 years of age and older: Brush teeth thoroughly, preferably after each meal or at least twice a day, or as directed by a dentist or doctor. Instruct children under 6 years of age in good brushing and rinsing habits (to minimize swallowing). Supervise children as necessary until capable of using without supervision. Children under 2 years of age: Consult a dentist or doctor." 21 C.F.R. § 355.50(d)(1)(i).

Despite having considered ingestion risks and safety for children's use, the FDA does not require sellers of fluoride toothpastes to include instructions about how much toothpaste to use, restrict what flavors are permitted, or warn about the possible effects of ingesting fluoride. *See, e.g.*, ¶¶ 99-113. Instead, the Anticaries Monograph reflects the FDA's conclusion that fluoride-containing products may be safely

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administrative order governing anticaries drug products appears at Final Administrative Order OTC000034, https://rb.gy/nttmi8.

used by children provided they are supervised and instructed to "minimize swallowing." *E.g.*, 21 C.F.R. § 355.50(d)(1)(i).

Pursuant to the Anticaries Monograph, Colgate manufactures and sells certain fluoride toothpaste products for children, including its Kids Toothpaste with Fluoride, Anticavity & Cavity Protection Toothpaste ("Kids Cavity Protection"), Kids Watermelon Burst Toothpaste ("Watermelon Burst"); Kids Unicorn Toothpaste Pump with Fluoride ("Unicorn Pump"), and a number of Tom's of Maine's Fluoride Anticavity Toothpaste ("Tom's Anticavity")[3] products (collectively, the "Products"). ¶¶ 119, 198, 199, 208, 212, 218. Plaintiffs allege that the packaging deceived them into believing the Products were "specially formulated to be safe for young children to ingest without need to limit how much [tooth]paste goes on the brush." ¶¶ 206, 210, 216. Plaintiffs then point to features like the word "KIDS," "bubble fruit," and "watermelon" flavors, a picture of a unicorn, as well as the ADA seal of approval and one product's toothbrush-and-toothpaste image, to try to support their theory. ¶¶ 201-03, 209, 215, 222. Plaintiffs omit from their allegations the actual instructions for use found on each and every Product label.

This omission is glaring considering Plaintiffs' alleged injuries. Despite pages of irrelevant and inflammatory allegations about the potential risks to children from *ingesting* fluoride, Plaintiffs do not assert their children ever ingested toothpaste or were harmed by alleged overuse of the Products. *See* ¶¶ 30-118 (no alleged physical injury); 235 ("Plaintiffs do not seek recovery for any personal injuries"). Rather, they claim solely economic loss, based on the theory that they "purchased more of the Products, and/or paid more per brushing, than they would have if they had known the truth" and they "would have ensured their child used the recommended amount of paste." ¶¶ 232-33, 235. But the "recommended amount of paste" that Plaintiffs allege they wish they had known is plainly disclosed in the "Drug Facts"

[3] Plaintiffs acknowledge that the Tom's Anticavity product is a "Tom's of Maine" product (¶ 58), and they include no specific factual allegations establishing Colgate's involvement in the manufacture and sale of this product. For convenience and efficiency, because Plaintiffs' pleading deficiencies apply equally to the Tom's Anticavity product, Colgate addresses all challenged Products together in this Motion. But Colgate notes that any claims related to the Tom's Anticavity product are subject to dismissal for the additional reason that Plaintiffs have not named the correct defendant, and Colgate accordingly reserves all rights. *See Sud v. Costco Wholesale Corp.*, 229 F. Supp. 3d 1075, 1081 (N.D. Cal. 2017), *aff'd*, 731 F. App'x 719 (9th Cir. 2018) (dismissing on standing grounds where plaintiffs failed to sufficiently "allege that the prawns they purchased were sourced by either of the CP Defendants").

section of *every Product's label*. Exs. A-D[4] (Product Labels) (directing "children 2 to 6 years" to "***use only a pea sized amount*** and supervise child's brushing and rinsing (to minimize swallowing)" and directing "children under 2 years" to "ask a dentist or physician"). The Products' "Warnings" and "Directions" include additional statements that dispel any notion that the Products are safe for young children to ingest in unlimited quantities. *See, e.g.*, Exs. A-D ("**Keep out of reach of children under 6 years of age**, if more than used for brushing is ***accidentally swallowed***, get medical help or contact a Poison Control Center right away.") (bold emphasis in original).

Plaintiffs nevertheless seek recovery of economic losses for alleged violations of California's Unfair Competition Law, Cal. Bus. & Prof. Code § 17200 ("UCL"); Illinois's Consumer Fraud and Deceptive Business Practices Act, 815 ILCS § 505/2 ("ICFA"); and New York's General Business Law §§ 349-50 ("GBL").[5]

IV. LEGAL STANDARDS

Under Rule 12(b)(1), dismissal for lack of Article III standing is proper where plaintiffs have not "clearly allege[d] facts demonstrating" that they "(1) suffered an injury in fact, (2) that is fairly traceable to the challenged conduct of the defendant, and (3) that is likely to be redressed by a favorable judicial decision." *McGee v. S-L Snacks Nat'l*, 982 F.3d 700, 705 (9th Cir. 2020) (cleaned up) (citing *Spokeo, Inc. v. Robins*, 578 U.S. 330, 338 (2016)). In response to a Rule 12(b)(1) motion, "the opposing party bears the burden of establishing the court's jurisdiction." *Wilson v. ColourPop Cosms., LLC*, 2023 WL 6787986, at *2 (N.D. Cal. Sept. 7, 2023) (Thompson, J.).

Under Rule 12(b)(2), dismissal for lack of personal jurisdiction is warranted where plaintiffs do not meet their burden of establishing for each claim an "affiliation between the forum and the underlying

[4] Exhibits A-D are attached to the concurrently filed Declaration of Robyn Bladow. The Court may consider these exhibits, which are true and correct copies of the Products' labels, because the Complaint incorporates them by reference. *See* Colgate's Request for Judicial Notice; *Hadley v. Kellogg Sales Co.*, 243 F. Supp. 3d 1074, 1087 (N.D. Cal. 2017) ("Courts addressing motions to dismiss product-labeling claims routinely take judicial notice of images of the product packaging.")

[5] Plaintiffs Verbish, Doutherd, Cherry, Recek, and Lazar (the "California Plaintiffs") bring claims individually and purportedly on behalf of a California class under the UCL. ¶¶ 248, 255, 263. Plaintiffs Burleigh, Clayborne, Hodge, Goel, and Cook (the "Illinois Plaintiffs") bring claims individually and purportedly on behalf of an Illinois class under the ICFA. ¶¶ 275-76. Plaintiffs Rivera, Cratsley, Roseboro, and Hook (the "New York Plaintiffs") bring claims individually and purportedly on behalf of a New York class under the GBL. ¶¶ 283-84.

controversy, principally, [an] activity or an occurrence that takes place in the forum State." *Bristol-Myers Squibb Co. v. Superior Ct.*, 582 U.S. 255, 264 (2017).

As to whether Plaintiffs state any valid claim for relief under Rule 12(b)(6), their Complaint "must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). A court need not blindly accept conclusory allegations, unwarranted deductions of fact, or unreasonable inferences. *Sprewell v. Golden State Warriors*, 266 F.3d 979, 988 (9th Cir. 2001). Additionally, Rule 9(b)'s heightened pleading standard applies here because Plaintiffs' claims sound in fraud. ¶¶ 242(a), 226, 227, 230, 249, 264, 276, 284; *see also Kearns v. Ford Motor Co.*, 567 F.3d 1120, 1125 (9th Cir. 2009). Plaintiffs must therefore "state with particularity the circumstances constituting fraud or mistake," Fed. R. Civ. P. 9(b), and identify the "who, what, when, where, and how" of the fraudulent misconduct, "as well as 'what is false or misleading about [it], and why it is false.'" *Cafasso v. Gen. Dynamics C4 Sys., Inc.*, 637 F.3d 1047, 1055 (9th Cir. 2011). Lastly, the Court may consider material outside of the complaint when the complaint incorporates the information by reference and necessarily relies on it. *See Eidmann v. Walgreen Co.*, 522 F. Supp. 3d 634, 641 (N.D. Cal. 2021).

Alternatively, the Court may strike under Rule 12(f) "any redundant, immaterial, impertinent or scandalous matter." *See Mireskandari v. Daily Mail & Gen. Tr. PLC*, 2013 WL 12129642, at *1 (C.D. Cal. July 31, 2013).

V. ARGUMENT

A. Plaintiffs Have Not Pled Article III Standing.

Plaintiffs do not bring claims for personal injury, emotional harm, or injunctive relief. ¶ 235. Instead, Plaintiffs' sole alleged injury is economic. ¶¶ 233-34. They seek to recover for the immeasurable quantity of extra toothpaste they allegedly allowed their children to use, claiming this excess was caused by the Product packaging. ¶¶ 230-35; *see also* ¶ 224 (alleging "[Plaintiffs] suffered economic loss … by obtaining fewer brushings per product"); ¶¶ 251, 259, 271, 279, 286 (alleging "less brushings per tube of toothpaste"). But Article III's "injury in fact" requires a plaintiff to "show that he or she suffered an invasion of a legally protected interest that is concrete and particularized." *McGee*, 982 F.3d at 705 (cleaned up). To demonstrate an economic injury in the context of a false advertising claim, "[a] plaintiff,

however, must do more than allege that she 'did not receive the benefit she *thought* she was obtaining.' The plaintiff must show that she did not receive a benefit for which she actually *bargained*." *Id*. at 706 (emphasis in original).

Here, although Plaintiffs' sole purported injury is based on number of brushings per tube, they do not allege Colgate made any representation about how many brushings each Product would yield. So, while a plaintiff can theoretically satisfy the injury in fact requirement by showing they "paid more for a product than [they] otherwise would have due to a defendant's false representations about the product" (*id*. at 706-07), Plaintiffs do not plead facts to support such a theory here. In fact, Plaintiffs do not plead *any* facts related to how many brushings they expected any toothpaste tube to yield, let alone any representations by Colgate regarding a promised number of brushings.

Instead, Plaintiffs take issue with Colgate's alleged "kids-branded" packaging, display of the ADA seal,[6] and a toothbrush-and-toothpaste graphic on one of the Products that they allege shows a "full strip" of toothpaste.[7] Plaintiffs allege these labeling features caused them to believe, *contrary to what the labels actually say* (*supra* III; Exs. A-D), that the Products were "specially formulated to be safe for young children to ingest without need to limit how much of the toothpaste to put on the brush." ¶¶ 201, 209, 215, 222. But under either an overpayment or a benefit-of-the-bargain theory, economic injury in this context requires a plaintiff to plead a misrepresentation that was "included in the bargain" or that caused her to "pay more for a product than she otherwise would have." *McGee*, 982 F.3d at 706-07. Plaintiffs complain that they paid too much for the number of brushings they received, but because Colgate did not promise any set number of brushings, Plaintiffs fail to meet even the "irreducible constitutional minimum" of demonstrating their nonexistent injury is "fairly traceable to the challenged action of the defendant." *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992). Moreover, Plaintiffs cannot ignore what Colgate *does* direct on the Products labels regarding the amount of toothpaste to use, including, "children 2 to 6 years | use only a pea sized amount and supervise child's brushing and rinsing (to minimize swallowing)"; "**Keep out of reach of children under six**"; "If more than used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center right away." Exs. A-D (emphasis in originals).

[6] Not applicable to the Watermelon Burst product.

[7] Only applicable to the Kids Cavity Protection product.

Nor do Plaintiffs' allegations about the Products being represented as "safe to ingest" give rise to Article III standing based on economic loss from supposed lost brushings. Even assuming the baseless and unreasonable theory that such things as a "green sparkling swirl" or a unicorn signal to parents they should let their kids ingest toothpaste (again, contrary to the "Directions" printed on each carton and tube label, *supra* III), that still does not create any promise of brushings-per-tube.[8] *See Birdsong v. Apple, Inc.*, 590 F.3d 955, 961 (9th Cir. 2009) (holding benefit of the bargain theory failed because "[t]he plaintiffs' alleged injury in fact is premised on the loss of a 'safety' benefit that was not part of the bargain to begin with"); *Wilson*, 2023 WL 6787986, at *5 ("Even if Plaintiff assumed the ColourPop makeup she purchased contained only safe and healthy ingredients, her beliefs too were not included in the bargain."). Plaintiffs paid for and received every ounce of toothpaste they were promised, and nothing in their Complaint suggests otherwise. The Court should dismiss all claims under Article III.

B. The Court Lacks Personal Jurisdiction Over the Non-California Plaintiffs' Claims.

Even were this Court to find it has subject matter jurisdiction over Plaintiffs' claims, it should dismiss the Illinois and New York Plaintiffs' claims under Rule 12(b)(2) because the Court lacks personal jurisdiction over Colgate with respect to those claims. *See Bristol-Myers*, 582 U.S. at 264. *First*, the Court lacks general personal jurisdiction over Colgate in ***California*** because, by Plaintiffs' own allegations, Colgate is a "publicly traded corporation organized and existing under the laws of the State of ***Delaware***, having its principal place of business [in] ***New York, NY***[.]" ¶ 119. *See King v. Bumble Trading, Inc.*, 2020 WL 663741, at *2 (N.D. Cal. Feb. 11, 2020) ("For corporate defendants, general jurisdiction exists at its 'place of incorporation and principal place of business.'") (citation omitted)).

Second, absent general jurisdiction, for their claims to survive, Plaintiffs must establish specific personal jurisdiction, which requires an "affiliation between the forum and the underlying controversy, principally, [an] activity or an occurrence that takes place in the forum State." *See Bristol-Myers*, 582 U.S.

[8] Plaintiffs' challenge to one Product's toothbrush-and-toothpaste graphic that allegedly shows a "full strip" of toothpaste further undermines Plaintiffs' Article III injury argument. If, as Plaintiffs claim, the toothbrush somehow provides a "visual instruction" regarding how much toothpaste to use (¶¶ 202, 250(c)), then the number of brushings Plaintiffs were "promised" is the same number they received after using full strips of toothpaste. If they instead followed the clear "Directions" on the package and used less than a "full strip," then under their own injury theory they would have received a windfall. Under neither circumstance did they suffer any economic loss.

at 264. This Court lacks specific jurisdiction over the New York and Illinois Plaintiffs' GBL and ICFA claims because, with no relevant "activity or occurrence" in California, Plaintiffs' claims lack any connection with this forum. To establish personal jurisdiction, Plaintiffs plead only that "[t]his Court has personal jurisdiction over [Colgate] because the injuries upon which the ***California Plaintiffs'*** action are based ***occurred or arose out of activities … within the State of California***." ¶ 121. But the Court's personal jurisdiction over the California Plaintiffs' claims is irrelevant to the Illinois and New York Plaintiffs' claims. *Bristol-Myers*, 582 U.S. at 265 (explaining that "[t]he mere fact that *other* plaintiffs" in the same case asserted connections to California and "sustained the same injuries as did the nonresidents—does not allow the State to assert specific jurisdiction over the nonresidents' claims"); *In re Samsung Galaxy Smartphone Mktg. & Sales Pracs. Litig.*, 2018 WL 1576457, at *2 (N.D. Cal. Mar. 30, 2018) (applying *Bristol-Myers* and granting motion to dismiss out-of-state plaintiffs' claims); *Goldstein v. Gen. Motors LLC*, 445 F. Supp. 3d 1000, 1012 (S.D. Cal. 2020) (concluding "*Bristol-Myers* applies to named plaintiffs in class actions for federal courts sitting in diversity").

The Court should dismiss the New York and Illinois Plaintiffs' claims for this additional reason.

C. Plaintiffs' Claims Are Preempted by the FDCA.

Plaintiffs' claims fail for another reason: they seek to impose additional requirements via state law beyond what federal law requires and are therefore preempted. Responding to the lack of uniformity resulting from 50 different state standards for OTC drug labels, in 1977, Congress added to the Federal Food, Drug, and Cosmetic Act ("FDCA") an express preemption clause (Section 379r), which preempts state laws that "establish or continue in effect any requirement—(1) that relates to the regulation of a[n OTC] drug … and (2) that is different from or in addition to, or that is otherwise not identical with, a requirement under" the FDCA. 21 U.S.C. § 379r(a). Section 379r "often preempts state law that extends beyond federal law in *any respect*, meaning that federal law acts as a floor and a ceiling for state requirements." *In re Oral Phenylephrine Mktg. & Sales Pracs. Litig.*, 2024 WL 4606818, at *2 (E.D.N.Y. Oct. 29, 2024). "[T]he whole point of section 379r is that it is not up to private litigants—or judges—to decide what is 'false or misleading' [on OTC drugs]. It is up to the FDA." *Eckler v. Neutrogena Corp.*, 238 Cal. App. 4th 433, 454 (2015). The "touchstone of preemption under § 379r is the *effect* that a finding of liability on a particular claim would have." *Morgan v. Albertsons Cos., Inc.*, 2023 WL 3607275, at *4

(N.D. Cal. Mar. 13, 2023). "As long as [a] claim imposes a 'requirement' that is at variance with FDA regulations, it is [expressly] preempted." *Carter v. Novartis Consumer Health, Inc.*, 582 F. Supp. 2d 1271, 1283 (C.D. Cal. 2008). In other words, "preemption is certainly appropriate when a state law prohibits labeling that is *permitted* under federal law. But it is also appropriate when a state law prohibits labeling that is *not prohibited* under federal law." *Wiltz v. Chattem, Inc.*, 2015 WL 3862368, at *1 (C.D. Cal. May 8, 2015).

Here, Section 379r expressly preempts Plaintiffs' claims because the Products are governed by the Anticaries Monograph, which establishes conditions under which OTC fluoride toothpastes are "safe, effective, and not misbranded." 21 C.F.R §§ 330.1, 355.1, *supra* III. And while Plaintiffs accuse Colgate of violating the general prohibition on "false and misleading labeling" codified at 21 U.S.C. § 352(a), their accusations are erroneous legal conclusions (and are no less preempted). ¶¶ 183, 196 n.100, 227. Indeed, the FDA has specifically declared fluoride toothpastes "***not misbranded*** if [they] meet[] … each of the conditions contained in [the] applicable monograph." 21 C.F.R. § 330.1; *see also id.* § 355.1. The Product labels at issue here undisputedly contain the warnings and instructions required by the Anticaries Monograph. Accordingly, if Plaintiffs were permitted to proceed on their § 352(a)(1) theory, "any finding of liability in [their] favor would conflict with preexisting regulations" deeming the Products "not misbranded," and "would do exactly what Congress, in passing § 379r, sought to forbid: using state law causes of action to bootstrap labeling requirements that are 'not identical with' federal regulation." *Seale v. GSK Consumer Health, Inc.*, 718 F. Supp. 3d 1208, 1222 (C.D. Cal. 2024) (rejecting § 352(a) misbranding argument and finding labeling claims preempted where product complied with monograph); *see also Bowling v. Johnson & Johnson*, 65 F. Supp. 3d 371, 377 (S.D.N.Y. 2014) (finding plaintiffs' claim that toothpaste labeling violates the FDCA misbranding provision "foreclosed for substantively the same reason that their state law claims are foreclosed: both seek to supercede the FDA's regulatory authority"); *Critcher v. L'Oreal USA, Inc.*, 959 F.3d 31, 38 (2d Cir. 2020) (rejecting plaintiffs' attempt to use similarly broad misbranding statute "to impose [] *additional* labeling requirements" not in the federal statute, because doing so would "disrupt what Congress intended to be a uniform—and federally-led—regulatory scheme"). Ultimately, because the Anticaries Monograph (i) does not prohibit Colgate from using the packaging claims, features, or graphics that Plaintiffs challenge (*see* ¶¶ 201, 202, 209, 215, 222);

and (ii) does not require Colgate to include any additional disclosures, all of Plaintiffs' state-law claims challenging the packaging are expressly preempted by federal law and should be dismissed.

First, Section 379r preempts Plaintiffs' claims that challenge existing aspects of the Products' Anticaries Monograph-governed labeling. Plaintiffs challenge Colgate's alleged "kids-branded" packaging, including the colors used and flavors offered, as well as one Product's toothbrush-and-toothpaste graphic that allegedly shows a "full strip" of toothpaste. *Supra* III; ¶¶ 202-40. But these claims are preempted because the FDA already considered their substance—*i.e.*, whether the products are appropriate for children and how warning information must be presented—and decided not to prohibit such language, colors, imagery, or product features in the final Anticaries Monograph. *See Colella v. Atkins Nutritionals, Inc.*, 348 F. Supp. 3d 120, 137 (E.D.N.Y. 2018) (claims preempted because "while the FDA may not have considered the exact language addressed … it had clearly addressed the substance of the claims at issue").

That the Anticaries Monograph does not require Colgate to include instructions about how much toothpaste to use or restrict what flavors are permitted is no mistake. In developing the Anticaries Monograph, the FDA considered the exact concerns Plaintiffs raise in their Complaint and determined that the warnings and directions required in the Anticaries Monograph were sufficient. For example, the FDA considered "that young children are most susceptible to mild fluorosis as a result of improper use and swallowing of a fluoride dentifrice product" and accordingly required labels to state: "Children under 2 years of age: Consult a dentist or doctor." 60 Fed. Reg. 52474, 52487. The FDA likewise agreed that "children should be trained how to brush their teeth so that they will obtain the desired benefit of toothbrushing without swallowing excessive amounts of toothpaste, which would increase their risk of fluorosis," and to that end required that labels "[i]nstruct children under 6 years of age in good brushing and rinsing habits (to minimize swallowing)." *Id.* at 52488. In crafting these instructions, the FDA underscored that it is the *parents'* obligation "to assure themselves that their children are learning the proper use of dentifrices," and that "the labeling should make this point without being unnecessarily overcautious or alarmist" about using fluoride toothpaste with children. *Id.*

Because the FDA carefully considered the warnings and directions to be provided on fluoride toothpaste labels sold under the Anticaries Monograph and determined the language necessary to ensure

the products were "not misbranded" (21 C.F.R. § 355.1), there is no reason to believe that a court or private litigant "would come to a more informed conclusion regarding the label that should be put on a product than the FDA." *Goldstein v. Walmart, Inc*., 637 F. Supp. 3d 95, 113 (S.D.N.Y. 2022); *see also Bowling*, 65 F. Supp. 3d at 377 ("[T]he whole point of section 379r is that it is not up to private litigants—or judges—to decide what is 'false or misleading.' It is up to the FDA."). It is irrelevant, as Plaintiffs plead, that the Anticaries Monograph "does not require the label of fluoride toothpastes to depict full strips of toothpaste," "does not require fluoride toothpastes to be packaged to look like candy or food products," "does not require fluoride toothpastes to taste like candy or fruit[,]" etc. ¶¶ 191-97. "[W]hether the FDA specifically approved the use of [the challenged statements] is beside the point," *Novotney v. Walgreen Co.*, 683 F. Supp. 3d 785, 792 (N.D. Ill. 2023), and courts routinely hold that similar state-law challenges to labeling statements that are either expressly permitted or not expressly prohibited under FDA monographs, are preempted.

For instance, in *Wiltz v. Chattem*, the court (applying the same Anticaries Monograph) found challenges to the claim that an oral care product "Rebuilds Tooth Enamel" were preempted because the relevant monograph was "silen[t] as to whether this type of claim is misleading" and, accordingly, "this type of claim was expressly not prohibited under federal law." 2015 WL 3862368, at *2. This Court's decision in *Silva v. Haleon US Inc.*, applied similar reasoning. 2024 WL 5059174 (N.D. Cal. Dec. 2, 2024) (Thompson, J.). The *Silva* plaintiffs alleged that the defendant "deceptively represent[ed] that [Sensodyne Pronamel products] 'Rebuild[],' 'Restore[],' and 'Repair' tooth enamel—*i.e.*, that the products purport to reverse enamel loss" because "the plain meaning of these terms plausibly leads reasonable consumers to believe that the Products bring back and restore lost enamel." *Id.* at *1. But, in rejecting the plaintiffs' argument that "the focus should be on 'whether the challenged statements are *authorized* by the FDA's regulation or other pronouncements of similar legal effect,'" this Court held that because the Anticaries Monograph contains "no prohibition of using the term 'rebuilds' or 'restores,'" to "prohibit Defendants' use of certain terms (*i.e.* rebuilds and restores) based on Plaintiffs' claims here would mean that private litigants and judges are deciding what is false or misleading." *Id.* at *4, *6, *7. The same logic warrants dismissal here. *See also Bowling*, 65 F. Supp. 3d at 373, 376 (Anticaries Monograph preempted claim that "Restores Enamel" on mouthwash label was misleading because the Anticaries Monograph was silent as

to the phrase "Restores Enamel" and neither *prohibited* the challenged statement nor *required* any disclosure, explanation, or warning concerning enamel restoration).

Second, to the extent Plaintiffs' claims arise out of any alleged non-disclosures, they are likewise preempted. For instance, Plaintiffs allege that Colgate improperly omitted ADA guidance from some of its Products while using the ADA seal of approval. ¶¶ 201(d), 215(d), 222(f), 250(b). Plaintiffs' claim "that some other terminology is necessary to ensure that the label is not misleading" would impermissibly "impose[] requirements that are different from, additional to, or otherwise not identical with, the requirements of the FDCA," and is therefore preempted. *Novotney*, 683 F. Supp. 3d at 792 (claims challenging aspect of label not required by monograph were expressly preempted). Similarly, the court in *Seale* found that a complaint sought "to impose upon Defendant an *actual requirement* of either explicit disclosure or compelled omission regarding the similarity of its children's and adult cough and cold medications." 718 F. Supp. 3d at 1222. But because that requirement was "imposed by neither the FDCA nor the FDA's relevant monograph," the claims were expressly preempted because they were "precisely what § 379r(a)(2) aims to prevent." *Id.* Likewise, in *Youngblood v. CVS Pharm.*, the court found that Section 379r expressly preempted claims concerning CVS's OTC acetaminophen product marketed for use with infants. 2021 WL 3700256, at *3. Because "children's acetaminophen products complying with the labeling requirements" of the relevant monograph "are not misbranded," federal law expressly preempted their "claims seeking additional, gratuitous representations." *Id.* ("Adjudicating Plaintiffs' claims in their favor would penalize Defendants for declining to include labeling representations beyond what the [monograph] requires for children's acetaminophen products.").

Thus, because Plaintiffs' claims challenging Colgate's existing labeling and alleged nondisclosures seek to impose requirements that are different from, in addition to, or otherwise not identical to the Anticaries Monograph, they are expressly preempted and should be dismissed. *See Kanter v. Warner-Lambert Co.*, 99 Cal. App. 4th 780, 795 (2002).[9]

[9] Plaintiffs' attempt to base any state-law claim (including their UCL unlawful-prong claim) on Colgate's supposed noncompliance with FDA regulations (*e.g.*, ¶¶ 226, 258) is likewise impliedly preempted, as discussed *infra* (V)(D)(2).

D. The California Plaintiffs Fail to State Any UCL Claim.

Plaintiffs' consumer protection claims fail for additional reasons. Beginning with the California Plaintiffs, their claims under the fraudulent and unfair prongs of the UCL (¶¶ 247-53; 262-73) fail because they do not plausibly plead any fraudulent or deceptive conduct—let alone with the particularity Rule 9(b) requires. And their claim under the unlawful prong (¶¶ 254-61) fails because it is predicated exclusively on a supposed violation of the FDCA and is therefore preempted. Finally, Plaintiffs' UCL claims fail for the additional reason that they do not allege they lack an adequate legal remedy.[10]

1. Plaintiffs' fraudulent and unfair UCL claims fail because Plaintiffs do not plead any conduct that would deceive a reasonable consumer.

The California Plaintiffs' fraudulent and unfair UCL claims "must state with particularity the circumstances constituting fraud." *See Kearns*, 567 F.3d at 1125 (applying 9(b) to UCL claims).[11] Where false labeling claims are asserted under the UCL (¶¶ 167-76), the "reasonable consumer" test governs. *See McGinity v. Procter & Gamble Co.*, 69 F.4th 1093, 1097 (9th Cir. 2023). Under the reasonable consumer test, Plaintiffs must establish "that a significant portion of the general consuming public or of targeted consumers, acting reasonably in the circumstances, could be misled." *Id.* In making this determination, the Court should not consider the reasonable consumer as the "least sophisticated consumer." *Becerra v. Dr Pepper/Seven Up, Inc.*, 945 F.3d 1225, 1228 (9th Cir. 2019). Nor is the reasonable consumer "a chump, too doltish or careless to engage in" a "simple analysis" concerning product features they care about or to consult the label for clarifying information. *La Barbera v. Olé Mexican Foods Inc.*, 2023 WL 4162348, at *11 (C.D. Cal. May 18, 2023). With this "reasonable consumer" framework in mind, Courts may grant motions to dismiss consumer protection claims "on the basis that the alleged misrepresentations were not false, misleading, or deceptive as a matter of law." *Joslin v. Clif Bar & Co.*, 2019 WL 5690632, at *6

[10] Plaintiffs also lack statutory standing to bring their UCL claims, as they need to plead *both* an injury in fact and that they "ha[ve] lost money or property as a result of the unfair competition." *Kwikset Corp. v. Superior Ct.*, 51 Cal. 4th 310, 322 (2011). For the same reasons Plaintiffs lack Article III standing to bring *any* claims in this Court (*supra* V(A)), they lack statutory standing under the UCL. *See, e.g.*, *Wilson*, 2023 WL 6787986, at * 6.

[11] Plaintiffs' unfair and fraudulent UCL claims are premised on the exact same alleged deception (*compare* ¶ 250, *with* ¶¶ 267-71), *i.e.* they "overlap[] entirely," and may therefore be considered and disposed of together. *See Kearns*, 567 F.3d at 1127 (holding that where plaintiff alleges a unified fraudulent course of conduct and grounds his claims in fraud, and his claims under the fraudulent prong are inadequately pled, the court need not "separately analyz[e] … claims under the unfairness prong of the UCL."); *Eidmann*, 522 F. Supp. 3d at 647.

(N.D. Cal. Aug. 26, 2019); *see also Werbel ex rel. v. Pepsico, Inc.*, 2010 WL 2673860, at *3 (N.D. Cal. July 2, 2010) (finding no reasonable consumer would believe "Crunch Berries" in Cap'n Crunch cereal provide "nutritional value derived from fruit").

Here, the California Plaintiffs advance three theories of deception: (i) that the colors, flavors and imagery on the Products mislead consumers into thinking toothpaste is safe for children to eat (¶¶ 201, 209, 215, 222); (ii) that the ADA's seal of approval further misleads consumers into thinking toothpaste is safe to eat (¶¶ 202, 215, 222); and (iii) that a graphic of a strip of toothpaste over a toothbrush on the packaging of one of the challenged Products somehow instructs consumers to use too much toothpaste (¶ 202), contrary to specific "Directions" on every Product label (Exs. A-D). Plaintiffs' UCL claims should be dismissed because they fail to plausibly allege, let alone plead with particularity, any false or deceptive statements that would mislead a reasonable consumer.

a. Reasonable consumers are not likely to be deceived by the Products' packaging.

The California Plaintiffs allege that certain colors, flavors, and imagery on the Product labels "deceptively convey … that the toothpaste inside the tube is specially formulated to be safe for young children to ***ingest*** without need to limit how much of the toothpaste to put on the brush." ¶¶ 201, 209, 215, 222.[12] But Colgate's packaging is not deceptive because the Products ***can*** be used by kids. And Colgate's packaging says nothing to encourage (or even suggest) a child should *ingest* the toothpaste. Far from it. The labels instead instruct parents regarding ***how*** their kids should use the Products, including ***how much*** product, directing parents to "***supervise***" their children and to "***minimize swallowing***." Exs. A-D ("children 2 to 6 years | use only a pea sized amount and supervise child's brushing and rinsing to minimize swallowing"; "children under 2 years | ask a dentist or physician") (emphasis in original). These "Directions" can and should be considered because courts do not evaluate product labels in a vacuum; they consider all information available to consumers, and to the extent there is any ambiguity, they refer

[12] Specifically, the California Plaintiffs allege the following "deceptive attributes" (¶¶ 206, 210, 216, 223): (1) the Kids Cavity Protection label "prominently displays the word 'KIDS,'" uses the flavor "bubble fruit," says the product is free of "parabens, preservatives, and sugar" (¶ 201); (2) the Watermelon Burst label uses "crayon-like rainbow" text and says the product has a "sweet watermelon taste and scent" and is "SUGAR FREE" (¶ 209); (3) the Unicorn Pump label contains a cartoon image of a unicorn, has a "bubble fruit" flavor (¶ 215); and (4) the Kids Natural label uses the words "Kid's" and "Natural" and displays images of fruit as well as "silly names for the fruit flavors" and cartoon graphics (¶ 222).

to the back label. *See McGinity*, 69 F.4th at 1099. In doing so, a court can properly "resolve [deception] claims based on its [own] review of the product packaging." *Buso v. ACH Food Co.*, 445 F. Supp. 3d 1033, 1037 (S.D. Cal. 2020); *Werbel*, 2010 WL 2673860, at *3.

Not only must the Court review the challenged "kids-branded" features in the context of the label as a whole, it should also consider the targeted consumer. *See McGinity*, 69 F.4th at 1097; *La Barbera*, 2023 WL 4162348, at *11. The reasonable consumers at issue here are *parents*, not children. *See, e.g.*, ¶¶ 31, 38, 45, 52, 58 (alleging parents purchased the Products for their minor children). And while Plaintiffs claim that Colgate employs "aggressive marketing tactics" like using "pictures of fruit" which may "signal *to a child* that toothpaste is intended to be consumed" (¶ 13)—children typically do not purchase toothpaste. A reasonable parent would not conclude that their child can eat toothpaste because of a picture of a unicorn (Ex. C), or a strawberry with a smiley face (Ex. D), or any of the other imagery Plaintiffs cite—because no reasonable parent believes toothpaste is food. *See Eidmann*, 522 F. Supp. 3d at 644 (finding "the depictions of children on the Infants' Product and Children's Product are cartoon-like illustrations, not photographs" and so "[i]t is hard to imagine that a reasonable consumer would believe the medicine is specially formulated for infants based on an illustration"); *Bohen v. ConAgra Brands, Inc.*, 2024 WL 1254128, at *7 (N.D. Ill. Mar. 25, 2024) (court must "account for all information available to consumers," including "general knowledge about the product"). And a reasonable parent would certainly consult the "Directions" if they had any question about the appropriate usage amount.

Plaintiffs also cite publicly available cautionary statements about ingesting too much fluoride-containing toothpaste products. *See, e.g.*, ¶¶ 125-26 (citing statements from FDA, CDC, and Journal of Public Health Dentistry). They then neglect to mention that every toothpaste product at issue here includes an FDA approved "Drug Facts" label, warning parents to "[k]eep out of reach of children under 6 years old" and "[i]f more than used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center right away." Exs. A-D. And reasonable consumers know to look for such usage instructions on OTC products. "Just as consumers are accustomed to seeing a product's ingredients listed by weight under the nutrition facts, so too are consumers accustomed to seeing the FDA-mandated 'Directions' on the back of an over-the-counter product." *Engram v. GSK Consumer Healthcare Holdings (US) Inc.*, 2021 WL 4502439, at *5 (E.D.N.Y. 2021) (cleaned up). For that reason, "it is not too much to expect a

reasonable consumer to review the directions on an" OTC drug "where, as here, a similar set of directions is present on all [OTC drugs] pursuant to FDA regulations." *Id.*

Because Plaintiffs do not plausibly allege the colors, flavors, or imagery constitute any affirmative misrepresentation, let alone instruct parents to let their kids ingest toothpaste in unlimited quantities—particularly in light of the accompanying warnings and instructions expressly intended to minimize swallowing—Plaintiffs have failed to plausibly establish (or plead with particularity) how the packaging would mislead a reasonable consumer parent. *See Moore v. Trader Joe's Co.*, 4 F.4th 874, 882 (9th Cir. 2021) ("[A] plaintiff's unreasonable assumptions about a product's label will not suffice."); *Lokey v. CVS Pharmacy, Inc.*, 2021 WL 633808, at *4 (N.D. Cal. Feb. 18, 2021) (finding no reasonable consumer would be deceived where OTC drug label included dosing instructions, concentrations of active ingredient, and "nothing about the labels is misleading about the products or their composition. To the contrary the labels are accurate."); *Rugg v. Johnson & Johnson*, 2018 WL 3023493, at *3 (N.D. Cal. June 18, 2018) (finding "it completely implausible that a reasonable consumer would understand the use of the term 'hypoallergenic' on a product's label to mean that the product" would not "have *any* [] negative effect").

b. Reasonable consumers are not likely to be deceived by the ADA seal of acceptance.

Plaintiffs also challenge the ADA seal of acceptance on the Kids Cavity Protection, Unicorn Pump, and Tom's Anticavity products, claiming it is misleading because Colgate does not disclose ADA guidance that "children under 3 should use no more than a smear of paste." ¶¶ 10 n.4, 202, 215, 222, 250.

The American Dental Association is a third-party trade organization (www.ada.org). The ADA seal on the Products states in full: "ADA Accepted: Helps Prevent Cavities" (Exs. A, C, D). Plaintiffs do not and cannot dispute that these Products are in fact certified by the ADA as "ADA Accepted" or that they "Help[] Prevent Cavities." Because Plaintiffs cannot dispute this certification, Plaintiffs' deception theory based on the ADA seal fails. *Bohen*, 2024 WL 1254128, at *7 (no deception where plaintiffs "do not allege … certification on the packaging is inaccurate"); *Sanchez v. Walmart Inc.*, 733 F. Supp. 3d 653, 671 (N.D. Ill. 2024) ("Plaintiff fails to state a claim for deceptive conduct … based on the MSC certification label" because "the certification communicates only that the product meets MSC' standards" a "statement that is factually true").

In any event, Plaintiffs do not allege how the ADA seal misleads reasonable consumers to conclude anything about how much Product to use. The ADA seal says nothing about how much toothpaste to put on the brush. And although Plaintiffs allege that the "ADA states children under 3 should use no more than a smear of paste" (¶¶ 202, 215, 222, 250), it is ***the FDA***, not the ADA, that sets the labeling standards for fluoride toothpaste products and has outlined the usage warnings and instructions that Colgate's product labels must include. *Supra* V(C). Plaintiffs' claims that Colgate misled or deceived them by including a true representation on some of the Products—that they are "ADA Accepted"—fail as a matter of law.

c. Reasonable consumers are not likely to be deceived by one Product's toothbrush-and-toothpaste graphic.

Additionally, Plaintiffs allege that the toothbrush-and-toothpaste graphic with a "full strip" of paste on the back of Kids Cavity Protection's packaging is "likely to deceive the consuming public into believing a full strip of toothpaste is a safe, recommended, and age-appropriate amount of paste to use." ¶ 250. Plaintiffs' theory assumes a parent-consumer will look at a stylized, cartoonish graphic (not even a real photograph) on the back of a label and then ignore the actual "Directions" on the side panel and on the tube itself. *See* Ex. A. The back-panel graphic cannot reasonably be construed as a direction or instruction for use—the "Directions" are. *Id.*; *see Eidmann*, 522 F. Supp. 3d at 644 (noting the challenged graphics were "cartoon-like illustrations, not photographs" and that "[i]t is hard to imagine that a reasonable consumer would believe the medicine is specially formulated for infants based on an illustration, especially one so simplistically one-dimensional"). And those "Directions" instruct, among other things, that children 2 to 6 use only "a pea-sized amount" of toothpaste and that parents should "supervise child's brushing and rinsing (to minimize swallowing)" and "ask a dentist or physician" for children under 2. Ex. A.

In any event, Plaintiffs' assertion that a toothbrush graphic would supplant the specific warning and drug fact information provided on the label in the minds of reasonable consumers is not plausible. *See Eidmann*, 522 F. Supp. 3d at 644 (finding product instructions and disclosures would be more instructive to reasonable consumer than illustrations); *Lokey*, 2021 WL 633808, at *5 ("What ultimately dooms Plaintiff's claims is that Defendant tells the consumer exactly what she is getting: the package actually discloses the fact that Plaintiff complains it omits."); *Hodges v. King's Haw. Bakery W., Inc.*, 2021 WL

5178826, at *6-7 (N.D. Cal. Nov. 8, 2021) (finding that a reasonable consumer cannot be "selectively blind" when viewing product labels); *Moore*, 4 F.4th at 881-82 (holding label which read "'100% New Zealand Manuka Honey' was not misleading to a reasonable consumer as a matter of law" because "other available information about [the product] would quickly dissuade a reasonable consumer from the belief that [the product] was derived from 100% Manuka flower nectar"). This is particularly true here, where the reasonable consumer is a *parent*, not a child. And a reasonable parent will not interpret a stylized graphic of a toothbrush with toothpaste as some sort of instruction regarding how much paste to use for their young children; that parent will instead be readily aware of and will refer to the instructions present on all OTC drug labeling to determine any guidance on product usage. *See supra* (V)(D)(1)(a).

Because the California Plaintiffs have failed to identify any representations that are deceptive or misleading to a reasonable consumer, their fraudulent and unfair UCL claims should be dismissed.

2. Plaintiffs' unlawful UCL claim is impliedly preempted.

Recognizing there is "no private right of action under FDCA," Plaintiffs allege violations of the FDCA as the "prerequisite" for their state-law claims, including as the sole basis for Plaintiffs Cherry and Recek's UCL "unlawful" claim. ¶¶ 28 n.21, 258.[13] Specifically, Plaintiffs' unlawful-prong UCL claim is predicated entirely on Colgate's alleged failure to place ***FDA-required*** warnings and directions on the immediate container label of the Unicorn Pump product, which Plaintiffs (wrongly) claim violates multiple FDCA provisions. ¶ 258. But this is precisely when implied preemption applies. *See Perez v. Nidek Co.*, 711 F.3d 1109, 1119 (9th Cir. 2013) (affirming dismissal of complaint where plaintiff's "fraud by omission claim 'exist[ed] solely by virtue of the FDCA … requirements'" because it amounted to an attempt to privately enforce the FDCA) (quoting *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 353 (2001)); *Nexus Pharms., Inc. v. Cent. Admixture Pharm. Servs., Inc.*, 48 F.4th 1040, 1050-51 (9th Cir. 2022) (holding where "[t]he purported state law violation is of a law that says in substance 'comply with the FDCA' … [t]he prohibition of private enforcement applies squarely, as does 'implied preemption'").

In fact, many courts in this Circuit—including this one—have rejected similar attempts by plaintiffs to avoid preemption by bringing UCL claims that would require the court to adjudicate alleged

[13] California Plaintiffs Cherry and Recek bring the UCL unlawful claim individually and purportedly on behalf of a subclass of California consumers who purchased the Unicorn Pump product. ¶ 255.

FDCA violations. *See, e.g.*, *Wilson*, 2023 WL 6787986, at *8 ("A plaintiff cannot plead around FDCA preemption if the existence of the claim arises from violation of the FDCA."); *Somers v. Beiersdorf, Inc.*, 467 F. Supp. 3d 934, 939-40 (S.D. Cal. 2020) ("As other courts have recognized, 'the [FDCA's] public enforcement mechanism is thwarted if savvy plaintiffs can label as arising under a state law for which there exists a private enforcement mechanism a claim that in substance seeks to enforce the FDCA.'"); *Telebrands Corp. v. Luminas Int'l LLC*, 2023 WL 6370902, at *4 (S.D. Cal. July 12, 2023) (finding UCL claim preempted by the FDCA, where defendants allegedly engaged in unlawful business practices by selling patches that did not comply with FDCA); *Argueta v. Walgreens Co.*, 2024 WL 5186825, at *6-7 (E.D. Cal. Dec. 20, 2024) (dismissing plaintiff's UCL claim "premised upon the lawfulness of Defendant's sale of the Products under the FDCA" because it is "barred under Section 337 and the doctrine of implied preemption"). The Court should dismiss the unlawful-prong UCL claim because it is improperly predicated on alleged FDCA violations and therefore is preempted.

3. Plaintiffs have not alleged inadequate remedies at law.

Also fatal to Plaintiffs' UCL claims is their failure to plead inadequate legal remedies. "A UCL action is equitable in nature; damages cannot be recovered." *Korea Supply Co. v. Lockheed Martin Corp.*, 29 Cal. 4th 1134, 1144 (2003). Thus, the remedies available to the California Plaintiffs under the UCL "are [] limited to injunctive relief and restitution." *Id.* (quoting *Cel–Tech Commc'ns, Inc. v. L.A. Cellular Tel. Co.*, 20 Cal.4th 163, 179 (1999)). Plaintiffs do not seek injunctive relief; rather, they appear to seek restitution because "Defendant has been unjustly enriched." ¶¶ 252, 260, 272, Prayer (C). The Ninth Circuit has repeatedly held that plaintiffs "must establish that [they] lack[] an adequate remedy at law before securing" equitable relief. *Sonner v. Premier Nutrition Corp.*, 971 F.3d 834, 844 (9th Cir. 2020). "[T]o entertain a request for equitable relief, a district court must have equitable jurisdiction, which can only exist under federal common law if the plaintiff has no adequate legal remedy." *Guzman v. Polaris Indus. Inc.*, 49 F.4th 1308, 1313 (9th Cir. 2022) (citation omitted). Here, Plaintiffs do not plead, even in conclusory fashion, that they lack an adequate remedy at law to address the economic harms they purportedly suffered. Therefore, their UCL claims fail. *See Stafford v. Rite Aid Corp.*, 2023 WL 2876109, at *4 (S.D. Cal. Apr. 10, 2023) (dismissing UCL claim as "facially deficient" where the "[c]omplaint does not even contain the phrase 'inadequate remedy at law'"); *Blain v. Liberty Mut. Fire Ins. Co.*, 2023 WL

3612390, at *3 (S.D. Cal. May 22, 2023) (similar).

Nor can the California Plaintiffs cure this defect by adding allegations that they lack an adequate remedy at law—they do not. Plaintiffs assert *only* a loss of money and/or loss in value (¶¶ 19, 207, 211, 224, 230-35), which is precisely the type of injury for which legal remedies are appropriate. *Sharma v. Volkswagen AG*, 524 F. Supp. 3d 891, 908 (N.D. Cal. 2021) (concluding plaintiff's allegation that they "suffered a *loss of money* and/or *loss in value*" "is exactly the type of injury for which legal remedies are appropriate"); *Gibson v. Jaguar Land Rover N. Am., LLC*, 2020 WL 5492990, at *3 (C.D. Cal. Sept. 9, 2020) (finding monetary damages would make plaintiff or the putative class whole where they "lost money or property"); *Kenney v. Fruit of the Earth, Inc.*, 2023 WL 3565076, at *3 (S.D. Cal. Apr. 3, 2023), *aff'd*, 2024 WL 4578981 (9th Cir. Oct. 25, 2024) (finding the court lacked equitable jurisdiction where damages were "adequate to remedy the harm Plaintiff suffered due to Defendants' allegedly misleading label"). And their choice to assert only equitable California claims does not render legal remedies inadequate either. *See Rodriguez v. FCA US LLC*, 2023 WL 3150075, at *4 (C.D. Cal. Mar. 21, 2023) (rejecting "Plaintiff's argument that his decision to assert a single claim under the UCL creates an inadequate legal remedy"). Because Plaintiffs' alleged injuries may be redressed by compensatory damages, their equitable claims under the UCL are improper and should be dismissed in their entirety.

E. The Illinois and New York Plaintiffs Fail to State Claims.

In addition to failing for lack of subject matter jurisdiction and personal jurisdiction, and in addition to being expressly (and impliedly) preempted by federal law, the Illinois and New York Plaintiffs' consumer protection claims fail for many of the same reasons as the California Plaintiffs' unfair and fraudulent UCL claims—they did not plead any deceptive conduct that would mislead a reasonable consumer, *supra* V(D)(1), let alone establish any injury, *supra* V(A).

The Illinois Plaintiffs' ICFA claim (¶¶ 274-81) requires "a deceptive act" and "actual damage." *Haywood v. Massage Envy Franchising, LLC*, 887 F.3d 329, 333 (7th Cir. 2018). Like UCL claims, it must be pled with particularity. *Korte v. Pinnacle Foods Grp.*, 2018 WL 1508855, at *6 (S.D. Ill. Mar. 27, 2018) (ICFA claims "alleging misrepresentation and deceptive practices" are "subject to the heightened pleading standard"). As with the California Plaintiffs, the Illinois Plaintiffs fail to plausibly allege an ICFA claim because they fail to allege any deceptive act that is misleading as a matter of law.

Supra V(D)(1); *see Rudy v. D.F. Stauffer Biscuit Co.*, 666 F. Supp. 3d 706, 719 (N.D. Ill. 2023) (dismissing ICFA claim "[g]iven the totality of information available to [plaintiff] and putative class members, the package's representations are not misleading as a matter of law"). Additionally, for the same reason their claims lack Article III standing, the Illinois Plaintiffs fail to plead actual damages. *Supra* V(A); *Camasta v. Jos. A. Bank Clothiers, Inc.*, 761 F.3d 732, 739 (7th Cir. 2014) (affirming ICFA dismissal where "[plaintiff] failed to provide any evidence that he paid more than the actual value of the merchandise he received").

Likewise, the New York Plaintiffs' GBL §§ 349 and 350 claims (¶¶ 282-88) require allegations of conduct that was "deceptive or misleading in a material way and that plaintiff [was] injured by reason thereof." *DaCorta v. AM Retail Grp., Inc.*, 2018 WL 557909, at *7 (S.D.N.Y. Jan. 23, 2018). The New York Plaintiffs fail to identify any materially misleading statements or injury. *Supra* V(D)(1); *Turnipseed v. Simply Orange Juice Co.*, 2022 WL 657413, at *3 (S.D.N.Y. Mar. 4, 2022) (highlighting that "numerous" courts have dismissed challenges to labels where nothing in the label itself would lead a reasonable consumer to understand the label as the plaintiff claims) (collecting cases). And for the same reason their claims lack Article III standing, the New York Plaintiffs fail to plead the actual injury necessary to state GBL claims. *Supra* V(A); *see DaCorta*, 2018 WL 557909, at *7 (finding plaintiff failed to connect her deception to any cognizable economic loss and that "the fact that [a] Plaintiff was deceived is not, standing alone, an 'actual injury'"). Given that the New York and Illinois Plaintiffs fail to allege injury or deceptive conduct that would mislead a reasonable consumer, their consumer protection claims should be dismissed.

F. Plaintiffs' Allegations Regarding Hypothetical Effects of Fluoride Should Be Stricken Under Rule 12(f).

Should the Court determine that any portion of Plaintiffs' claims survive, it should at minimum strike the "redundant, immaterial, impertinent, or scandalous matter" in Plaintiffs' Complaint under Rule 12(f). The Complaint is littered with inflammatory allegations that are entirely irrelevant to Plaintiffs' theory of economic harm. In particular, paragraphs 20-21, 24-27, and 124-60 should be stricken, because they serve no legitimate purpose in furthering Plaintiffs' claims and instead, assert a litany of hypothetical physical injuries from ingesting fluoride that no Plaintiffs allege to have suffered. *Mireskandari*, 2013 WL

12129642, at *4 ("Scandalous" matter includes allegations that improperly cast a "cruelly derogatory light on a party or person."). Here, Plaintiffs claim only to have "lost money" from getting "less brushings per tube," which has nothing to do with fluoride and the alleged effects of ingesting it. ¶¶ 213, 231, 234. *See Morrison v. Gonzales*, 2006 WL 8459777, at *2 (N.D. Cal. Jan. 30, 2006) (striking allegations that were not "necessary to the issues in this case" and did not "bear an essential or important relationship to the claim.").

Colgate does not seek to strike all allegations that discuss recommendations regarding safe use or known risks associated with fluoride (for instance, ¶¶ 5-17). Rather, it seeks a narrowly tailored order striking only those redundant, immaterial, or scandalous allegations that imply, without support, that ***Colgate's*** toothpaste Products can cause children catastrophic physical injury. *E.g.*, ¶¶ 20-21 (swallowing toothpaste "can potentially lead to death"); 24-27, 124-38 (detailed allegations regarding dental fluorosis, which no Plaintiffs claim to suffer); 139-45 (allegations of stomach flu symptoms); 146-52 (allegations regarding risk of ***death***); 153-60 (other health concerns). Because no Plaintiff asserts that they or their child suffered ***any*** physical injuries from the Products (¶ 142)—let alone the kinds of physical harm described in paragraphs 20-21, 24-27, and 124-60, the allegations are immaterial, impertinent, and scandalous and should be stricken under Rule 12(f). *See Mireskandari*, 2013 WL 12129642, at *5 ("Because plaintiff does not allege a cause of action based on this purported conduct, the allegations are immaterial and impertinent."); *see SST Sterling Swiss Trust 1987 AG v. New Line Cinema Corp.*, 2005 WL 6141290, *5 (C.D. Cal. Oct. 31, 2005) (striking allegations of racially discriminatory motive, because none of plaintiff's claims relied on or were supported by discriminatory treatment, and allegations were likely to "cast a cruelly derogatory light" on defendants).

VI. CONCLUSION

For the reasons set forth above, Colgate respectfully asks the Court to dismiss Plaintiffs' Complaint in its entirety with prejudice[14] or, alternatively, strike paragraphs 20-21, 24-27, 124-60.

[14] This Court may grant dismissal without leave to amend where "any amendment would be futile." *Leadsinger, Inc. v. BMG Music Pub.*, 512 F. 3d 522, 532 (9th Cir. 2008). Here, Plaintiffs cannot cure their pleading deficiencies with additional factual allegations, and therefore dismissal with prejudice is warranted.

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Respectfully submitted,

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